

REMARKS

The Board affirmed a rejection under 35 U.S.C. § 103(a) of Claims 17-24 as unpatentable over the combination of U.S. 4,708,874 (DeHaan et al), U.S. 5,552,159 (Mueller et al), and EP 204,596 (Drouin et al). That rejection should not be repeated, in view of the above-discussed amendment.

First of all, the presently-claimed subject matter was not before the Board, so there can be no issue of *res judicata* or issue preclusion.

Second of all, none of the above-described prior art, alone or in combination, suggests the presently-claimed invention. While Mueller et al disclose a solid depot drug form produced by melt extrusion at from 50° to 200°C, Mueller et al disclose and suggest nothing with regard to the presently-recited requirement of a hot-melt liquid state at a temperature of 100-150°C, nor the presently-recited glycerol monostearate, nor the presently-recited requirement that the glass transition temperature of the mixture of thermoplastic acrylic plastic and glycerol monostearate be no more than 20°K below the glass transition temperature of the thermoplastic acrylic plastic *per se*. While DeHaan et al disclose the use of glycerol monostearate (column 4, line 16), *inter alia*, it is disclosed as a degradable ingredient for the restraining phase therein, which is a restraining phase granulate that comprises one or more active ingredients dispersed in a matrix of an insoluble substance. Otherwise, DeHaan et al is no more relevant than Mueller et al. While the Board found that it appears that DeHaan et al's Example XI is the closest prior art (Decision at 9), this finding was based on the claims then pending. Such example can no longer be the closest prior art, since it does not use glycerol monostearate. Drouin et al disclose the use of glycerol palmito-stearate, *inter alia*, as a lipid excipient having an solubilizing or gelling capacity with regard to the polymer disclosed therein and a lubrication capacity to allow extrusion. But, Drouin et al discloses much lower extrusion temperatures, such as 65°C, which is

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substantially below the presently-recited minimum of 100°C. Applicants respectfully submit that the Declaration under 37 C.F.R. § 1.132 of named co-inventor Manfred Assmus, filed June 21, 1999 (first Assmus Declaration), and the Supplemental Declaration of Assmus, filed October 5, 1999 (supplemental first Assmus Declaration), are pertinent with regard to the present claims. The Board, at page 9, note 4, found the Assmus Declaration to not be effective, because it did not provide a comparison with the claimed invention. In reply, the point of the first Assmus Declaration was, and is, simply to show that operating at a temperature below the presently-recited minimum, such as disclosed by Drouin et al, produces a different, and inferior, product.

For all the above reasons, it is respectfully requested that the claims are patentable over the above-discussed prior art.

Applicants respectfully submit that all of the presently pending and active claims in this application are now in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

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